FEB - 8 2012

510(K) SUMMARY

Submitter:	Medos International Sàrl Chemin-Blanc 38 Le Locle, CH-NE 2400, Switzerland
Contact Person:	Eugene Bang Regulatory Affairs Associate DePuy Spine, Inc. Voice: (508) 977-3966 Fax: (508) 828-3797
Date Prepared:	November 4, 2011
Trade Name:	DePuy Pulse Thoracolumbar Screw System
Device Class:	Class III
Product Code(s):	NKB, MNI, MNH, KWP, KWQ
Common Name:	Appliance, Fixation, Spinal Intervertebral Body Appliance, Fixation, Spinal Interlaminal Orthosis, Spondyloisthesis Spinal Fixation Orthosis, Spinal Pedicle Fixation Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease
Classification Name:	Spinal Interlaminal Fixation Orthosis Spinal Intervertebral Body Fixation Orthosis Pedicle Screw Spinal System
Regulation Number:	888.3050, 888.3060, 888.3070
Predicate Devices:	Moss Miami System – K953915 Expedium System – K033901, K051024, K062174, K063156, K063741 K080313, K081898, K103490
Device Description:	The DePuy Pulse Thoracolumbar Screw System consists of a variety of rods, pedicle screws, connectors, set screws and other connection components used to build a spinal construct. The implant components can be rigidly locked into a variety of configurations, with each construct being made for the individual case. The DePuy Pulse Thoracolumbar Screw System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

Indications:

The DePuy Pulse Thoracolumbar Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The DePuy Pulse Thoracolumbar Screw System metallic components are intended for noncervical pedicle fixation and nonpedicle fixation for fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Materials:

Manufactured from ASTM F-136 implant grade titanium alloy.

Comparison to Predicate Device:

The substantial equivalence of the subject device to the predicates indentified above is based upon the equivalence of intended use, design (fundamental scientific technology), materials, manufacturing methods, performance, sterility, biocompatibility, safety and packaging design.

Non-clinical Test Summary:

The following mechanical tests were conducted:

- Static compression bending testing in accordance with ASTM F-1717 Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Mode. The acceptance criteria was/were met.
- Static torsion testing in accordance with ASTM F-1717 Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Mode. The acceptance criteria was/were met.
- Dynamic compression bending testing in accordance with ASTM F-1717 Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Mode. The acceptance criteria was/were met.

Clinical Test Summary:

No clinical tests were performed.

Conclusion:

Based on the predicate comparison and testing, the subject device DePuy Pulse Thoracolumbar Screw System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medos International, Sarl
% DePuy Spine, Inc.
Mr. Eugene Bang
325 Paramount Drive
Raynham, Massachusetts 02767

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Re: K113396
Trade/Device Name: DePuy Pulse Thoracolumbar Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWQ, KWP
Dated: January 6, 2012
Received: January 9, 2012

Dear Mr. Bang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113396

Device Name: DePuy Pulse Thoracolumbar Screw System

Indications For Use:

The DePuy Pulse Thoracolumbar Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

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Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113396